

Report Documentation Page				Form Approved OMB No. 0704-0188	
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1. REPORT DATE 01 SEP 2009		2. REPORT TYPE N/A		3. DATES COVERED -	
4. TITLE AND SUBTITLE Letters to the editor: Emergency tourniquet use.				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Kragh Jr. J. F.,				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) United States Army Institute of Surgical Research, JBSA Fort Sam Houston, TX 78234				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION/AVAILABILITY STATEMENT Approved for public release, distribution unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT					
15. SUBJECT TERMS					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 13	19a. NAME OF RESPONSIBLE PERSON
a. REPORT unclassified	b. ABSTRACT unclassified	c. THIS PAGE unclassified			

ized as well as double-blind trials in elderly patients) have demonstrated much faster achievement of discharge criteria and shorter hospital stay—all evidence-based and with a positive effect on morbidity.^{2–4} Therefore, comparison of postoperative outcomes in relation to surgical technique needs to be combined with updated evidence-based care principles to allow sufficient interpretation.⁵ We hope that such methodological issues will be considered in future trials, also to achieve the optimal potential for minimal invasive colorectal surgery.^{3,6}

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Reply:

We would like to thank Professor Kehlet for his useful comments in his letter to the editor about the Sigma-trial. His questions concern to what extent the comparison of postoperative outcomes in relation to surgical techniques (laparoscopic vs. open sigmoid resection in elective diverticulitis) need to be combined with updated evidence-based care principles.

This randomized study was performed as a multicentric trial between 2002 and 2006. During this period, progressive implementation of fast-track principles have been adopted. Moreover the primary aim of the study was not to demonstrate the advantages of perioperative care, in terms of the length of nasogastric tube, pain management, and hospital stay, but the differences in major morbidity, in a double-blinded way, after laparoscopic or open surgery.

The obtained hospital stay in our study reflects the European standards of laparoscopic and open surgery at the start of the trial in 2002 and probably even today. In the Sigma-trial clear discharge criteria were

established. Patients were discharged after having a bowel movement, tolerating solid food, and once they were able to walk properly, and felt comfortable with oral analgesia. Our results, 5 versus 7 days (statistically significant in favor of the laparoscopic group) is clearly longer than the data obtained by Basse et al and Kehlet et al of 2 days, but quite comparable with the 5 and 7 days obtained by King et al, comparing laparoscopic and open colonic resection within an enhanced recovery program.^{1,2,3}

Nevertheless some questions concerning the use of nasogastric tubes and pain management need explanation. Professor Kehlet addresses the high percentage of nasogastric tubes used postoperatively. This may be considered, indeed, as a protocol violation as our study stressed its removal at the end of the procedure. An explanation might be a liberal policy of nonremoval and reinsertion of nasogastric tubes at the recovery room by the anesthesiologists. Furthermore the “erroneous” nasogastric tubes were removed very soon after return from the recovery room, with a median duration of 0 days in the laparoscopic group versus 1 day in the open group.

Concerning pain score presentation, visual analogue scale (VAS)-pain scores were analyzed by repeated measures analysis, showing a significant lower level of pain in the laparoscopic group over the 5-day postoperative period (1.6 points on average; P 0.003). This significant reduction in VAS-pain score is presented in the results section. Moreover duration of systemic analgesia is given in table 4, indicating some benefit of the laparoscopic approach. On the other hand opioid requirements, which would have been helpful in adequate pain assessment, were not registered. Furthermore, in our study, 16% of the included patients received epidural analgesia instead of patient controlled analgesia and this may also be considered a violation of the protocol. To date thoracic epidural analgesia is favored over patient controlled analgesia, even though this technique seems to offer no advantages in combination with fast-track programs and there is no reduction of major morbidity rates in patients undergoing colorectal surgery.^{4,5} Moreover the current recommendations of the PROSPECT workgroup were not clear at the start of the trial in 2002. Since then, several studies on enhanced postoperative recovery programs have been published, showing improvements in terms of pain, mobilization, and hospital stay. In contrast, no significant reduction in major morbidity has been proven.³

In conclusion, we will try to answer the main question of this letter: “Are the

authors studying traditions or the effect of laparoscopic versus open surgery?”

The aim of this study was to demonstrate the possible benefits of the laparoscopic approach in terms of major morbidity. The Sigma-trial has shown a significant reduction in major morbidity if elective diverticulitis is approached laparoscopically instead of with an open approach. Moreover Professor Kehlet is right that the fast-track perioperative principles have contributed to a great extent to the enhancement of the quality of life of our patients and to the shorter hospital stay. Probably the combination of different factors of the fast-track treatment and the laparoscopic approach will provide the best outcome for our patients. Soon the LAFA trial will define the role of laparoscopic surgery as part of the fast-track principles.⁶

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Emergency Tourniquet Use

To the Editor:

I read with interest the important article by Kragh et al, *Survival With Emergency Tourniquet Use to Stop Bleeding in Major Limb Trauma*, published in the January 2009 issue of the *Annals of Surgery*.

I note that it states that 5 (3 American and 2 Iraqi) casualties with isolated limb injuries—who had indications for tourniquet application, but had no tourniquet used, all died. A survival rate of 0% versus 77% for those casualties with indicated tourniquets used ($P < 0.007$) is then quoted in the body of the article. However, the summary/abstract states that 0% versus 87% ($P < 0.001$). Which percentage is correct?

The 5 individuals who were alive in the field and did not have tourniquets applied apparently bled out in the presence of their fellow soldiers. This subgroup was then limb-matched with 13 others, all of whom had tourniquets applied, of whom 10 survived. The mean age in the nontourniquet group was 40.6 years (median: 46, range: 37–50) and that in the tourniquet group was 26.9 years (median: 25, range: 21–35). This is a significant difference in age profiles ($P < 0.004$, student t test). Could the authors comment on this difference as a potential confounding variable given the physiological effects of aging? Also, were these soldiers or contractors? The ages of the 5 dead would seem to be at odds with routine military service. Finally, was there an increased limb fasciotomy rate in the early hospital care of the survivors?

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Reply:

I thank Lt Col Parker for his interest and the *Annals of Surgery* for the opportunity to reply.

Both percentages are correct. As explained in the text, one deals with use and the other with indication.¹ Regarding age, the work was an observation, not an experiment, and so the cases were not randomized. That they did not have statistically similar ages is common in such situations. Our experience with age is evidently broader than Lt Col Parker's. The associations among age, hemorrhage, shock, and tourniquet use are inadequately evidenced in clinical practice and are infrequently studied in translational research. We saw servicepersons, contractors, and civilians. We did not emphasize job categorization since it was often unreliable and ultimately unproductive of knowledge.

Fasciotomy was beyond the scope of the work and was addressed elsewhere.^{2,3}

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Radiofrequency Ablation in the Treatment of Hepatocellular Carcinoma: The Need for Centralization

To the Editor:

We read with great interest the systematic review “*The Current Role of Radiofrequency ablation in the Management of Hepatocellular Carcinoma*,” in which Lau and Lai summarized the published data and clearly defined the role of radiofrequency ablation (RFA) as a treatment option for hepatocellular carcinoma (HCC).¹ As the authors pointed out, patients with smaller HCC (tumor diameter: ≤ 30 mm) have significantly better local control compared with patients with larger tumors. However, given the absence of randomized controlled trials, there is no consensus on whether to use the percutaneous, laparoscopic or intraoperative approach. In addition, we would like to emphasize the importance of operator-related expertise and hospital volume on the outcome of RFA for HCC treatment, as many clinicians are embarking on this therapy without paying much attention to its associated learning curve.

In patients with smaller tumors, we and others have found that the intraoperative approach appears to be superior to the percutaneous route.^{2,3} The open approach offers the advantage of direct examination for intra-abdominal extrahepatic disease and permits more precise positioning of the needle, resulting in lower local recurrence rates. A surgical approach also allows the use of a Pringle maneuver (temporary occlusion of both the hepatic artery and portal vein), which has been shown to result in larger coagulation zones when compared with treatment during normal hepatic flow.^{4,5} Despite the benefits of a lower complication rate, less invasiveness, and lower

costs that the percutaneous approach offers, they may not outweigh the long-term risk of local recurrence. Future studies should focus on comparing the ultrasound-guided percutaneous approach, the computed tomography-guided percutaneous approach, and the intraoperative approach.

If the number of peer-reviewed publications over the last several years is an indication of its application in clinical practice, we can conclude that there is a widespread increase in the use of RFA for the treatment of HCC. Using the keywords “radiofrequency ablation,” “liver,” and “carcinoma” in a search on PubMed, the number of articles published in 2000 was 21, gradually increasing to 148 articles last year. As many centers report their initial experience, the confounding effect of a learning curve needs to be kept in mind when interpreting data of RFA treatment in the published data. Experience from laparoscopic surgery, another minimally invasive treatment modality, has emphasized the importance of a learning curve when introducing new surgical procedures.^{6–8} Although such a learning curve is also likely to apply to the use of RFA for the treatment of HCC, RFA is often misperceived as a simple and safe technique, especially in contrast to hepatic resection.

Two groups previously described the influence of operator's experience with RFA on the outcome for the treatment of HCC. In 2004, Poon et al demonstrated that there is a significant learning curve when they compared their first group of 50 patients with a second group of 50 patients that underwent RFA treatment for malignant liver tumors (HCC, $n = 84$).⁹ The results showed a lower complication rate and a higher complete ablation rate in the latter group. In 2006, Hildebrand et al published a similar study comparing their first group of 42 patients with a second group of 42 patients treated with RFA for hepatic malignancies (HCC, $n = 6$).¹⁰ Although the complication rate for both groups was comparable, the complete ablation rate and the overall survival in the latter group were significantly higher. Both of these studies, therefore, showed a significant learning curve in the use of RFA.

Although we agree with the authors on the proposed indications for the use of RFA in the treatment of HCC, we would like to stress the importance of centralization of this treatment modality. As available published data demonstrates a considerable learning curve for RFA, an experienced and specialized RFA team could improve the patient's outcome significantly. We would advocate that the use of RFA as a treatment modality for HCC should be restricted to high volume, experienced hepatobiliary centers with a dedicated, multidisciplinary approach.